



K963568

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**510 (k) Summary**

Device Name:	Proprietary or Trade:	TIA Disposables -- 3-Ply Face Mask
	Common name:	3-Ply Mask
	Classification name:	Surgical Apparel (per 21 CFR 878.4040)
Labels & Labelings:	This product will be marketed to healthcare professionals at dentist's and doctor's offices, laboratories, clinics and hospitals through its intended use: PROTECTIVE APPAREL. Reference Appendix A and B for product labeling and applicant's advertising material catalog (in draft form pending the results of this submission).	
Intended Use	The <b>INTENDED MEDICAL USE</b> is to protect the healthcare personnel and patient from transfer of microorganisms, body fluids and particulate material.	
Substantial Equivalence:	<p>The Innovative Approach, Corp. believes that the above devices are <b>SIMILAR</b> to those in commercial distribution. These face masks are made of non-woven polypropylene and are to be worn as Protective Apparel.</p> <p>Both in their intended uses and/or in their physical characteristics, these items are similar to devices currently marketed by major US companies. Following is the list (by no means exhaustive) but aims at giving enough evidence to show <b>Substantial Equivalence</b>:</p> <ol style="list-style-type: none"><li>1. Instaguard Procedure Face Mask , Baxter</li><li>2. Surgine™ Face Mask, Johnson &amp; Johnson</li></ol>	
Test Results (means and or results)	<ul style="list-style-type: none"><li>• Synthetic Blood Penetration Resistance Test: Fluid Resistant</li><li>• Bacterial Filtration Efficiency (MIL Spec 36954C): 99.28</li><li>• Delta P (MIL Spec 36954C): 2.35</li><li>• Particle (MIL Spec 36954C): 3 microns</li><li>• Resistance to tears (NFPA 1999): 29.54 (max. tear resistance in lbs)</li><li>• Elongation (ASTM D5034-90): 12.82% (strain at maximum)</li><li>• Breaking Force (ASTM D5034-90): 23.25 (max. force in lbs)</li></ul>	

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The Innovative Approach, Corp.

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<b>Descriptive Comparison</b>	<b>Predicate</b>	<b>New Device</b>
Material Composition	Polypropylene	Polypropylene
Weave	Non-woven	Non-woven
Design	Earloop Tie-On	Earloop Tie-On
Anatomical sites protection	Nostrile and mouth	Nostrile and mouth
Sterility	Nonsterile	Nonsterile
Intended use	Protective	Protective Apparel
Target population	Healthcare professionals	Healthcare professionals
Use life	Disposable	Disposable
Where used	Medical & Dental offices	Medical & Dental offices
Baterial Filter Efficiency	98.5	98.5
Microns	3.2	3

Sincerely,



Elisa N. Pérez  
President